

Application Number 10/730,878
Response to final Office Action mailed August 3, 2007

REMARKS

This Amendment is responsive to the final Office Action dated August 3, 2007.
Applicant has amended claims 1, 9, 16, 19 and 20. Claims 1-20 are pending.

Amendments to the Specification

With the present Amendment, Applicant has amended paragraph [0051] of the originally-filed disclosure to add written description of the separable external leads that are shown in FIGS. 6A and 6B as originally-filed. The amendments to paragraph [0051] are fully supported by Applicant's disclosure as originally-filed, such as at FIGS. 6A-6B and FIG. 8B as originally filed and, therefore, adds no new matter.

Objection to Amendment Under 35 U.S.C. § 132(a)

The Amendment filed June 8, 2007 was objected to under 35 U.S.C. § 132(a), because it introduced new matter into the disclosure. The Office Action indicated that the Examiner was unable to find any mention of hermetic housings in paragraphs [0062]-[0064] of U.S. Patent Application Serial No. 10/731,869. However, in the Amendment filed June 8, 2007, Applicant referred to paragraphs [0062]-[0064] of published U.S. Patent Application Publication No. 2004/0176818 (the published application corresponding to U.S. Patent Application Serial No. 10/731,869), rather than paragraphs [0062]-[0064] of U.S. Patent Application Serial No. 10/731,869.

Support for the amendments to the claims in the Amendment filed June 8, 2007 can be found, for example, at paragraphs [0048]-[0050] of co-pending U.S. Patent Application Serial No. 10/731,869 as originally filed, which correspond to paragraphs [0062]-[0064] of published U.S. Patent Application Publication No. 2004/0176818. U.S. Patent Application Serial No. 10/731,869 was incorporated by reference in its entirety in Applicant's originally filed disclosure at paragraph [0002]. Thus, the amendments filed on June 8, 2007 add no new matter to the present application.

Withdrawal of the objection to the amendment filed on June 8, 2007 is respectfully requested.

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Claim Rejection Under 35 U.S.C. § 112

The final Office Action rejected claims 19 and 20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The final Office Action stated that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Support for hermetic housings was provided in Applicant's originally filed disclosure through incorporation of U.S. Patent Application Serial No. 10/731,869 by reference. As discussed above, support for the amendments to the claims can be found, for example, at paragraphs [0048]-[0050] of co-pending U.S. Patent Application Serial No. 10/731,869 as originally filed, which correspond to paragraphs [0062]-[0064] of published U.S. Patent Application Publication No. 2004/0176818. Material may be incorporated by reference to provide a written description of the claimed invention, as required by 35 U.S.C. § 112, first paragraph. See 37 C.F.R. § 1.57(c).

Withdrawal of this rejection is respectfully requested.

Claim Rejection Under 35 U.S.C. §§ 102(e) and 103(a)

The final Office Action rejected claims 1-13 and 15-18 under 35 U.S.C. § 102(e) as being anticipated by Berrang et al. (U.S. Patent No. 6,358,281, herein referred to as "Berrang"). In addition, claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang. Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the amended claims. Berrang fails to disclose or suggest each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability to modify its device to include such features.

For example, Berrang fails to disclose or suggest an implantable medical device comprising at least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules, and an overmold that at least partially encapsulates each of the housings, the overmold comprising a lead connection module configured to accept an external lead that is separable from the lead connection module, as recited by Applicant's independent claim 1.

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Similarly, with respect to independent claim 9 as amended, Berrang fails to disclose or suggest an overmold for a modular implantable medical device that includes a plurality of modules, the overmold comprising a first material configured to hold at least part of the housing of one of the modules, a second material coupled to the first material, and a lead connection module configured to accept an external lead that is separable from the lead connection module, the lead connection module being embedded within the overmold.

Additionally, Berrang fails to disclose or suggest an implantable medical device comprising at least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules, and an overmold that partially encapsulates each of the housings and defines a frame configured to fix a position of the at least two interconnected modules relative to one another, the overmold comprising a lead connection module configured to accept an external lead that is separable from the lead connection module, as recited by independent claim 16 as amended.

In support of the rejection of independent claims 1, 9 and 16, the Office Action characterized the intersection of bridge section 6 and junction 16 in Berrang as a lead connection module.¹ Applicant has amended independent claims 1, 9 and 16 to clarify that the lead connection module is configured to accept an external lead that is separable from the lead connection module. Based on the Office Action's characterization of the intersection of bridge section 6 and junction 16 in Berrang as a lead connection module, it appears that the Office Action is also characterizing the cables 7 and 8 in FIG. 1 of Berrang as external leads. Applicant does not agree that cables 7 and 8 are external leads. However, even if, for purposes of argument only, the cables 7 and 8 in Berrang are external leads, Berrang does not teach that the cables 7 and 8 are separable from the intersection of bridge section 6 and junction 16, i.e., the "lead connection module" according to the Office Action.

To the extent Berrang describes the cables 7 and 8 connecting to the device, Berrang merely states that, "[t]he microphone casing 14 and electrode array 10 are connected to the housing sections 2 and 3 via junction 16 where cables 7 and 8 merge."² The Office Action found that the cables 7 and 8 are integrally connected to the implantable device.³ In particular, with

¹ Office Action dated 8/3/07 at page 3, item 6.

² Berrang at col. 11, ll. 1-3.

³ Office Action dated 8/3/07 at page 4, item 11 and page 7, item 23.

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respect to the rejection of claims 6 and 7, the Office Action reasoned that "in Berrang, the lead connection module necessarily includes a mechanical lead securing mechanism because the lead is attached to the device and is tool-less because it is integral."⁴ Thus, because Berrang describes cables 7 and 8 that are integral with the device and does not contemplate any other configuration of the cables 7 and 8, Berrang fails to disclose or suggest a lead connection module configured to accept an external lead that is separable from the lead connection module, as recited by amended independent claims 1, 9, and 16.

Berrang also fails to disclose or suggest at least two interconnected modules that each comprise a respective housing to house the respective module, and an overmold that at least partially encapsulates each of the housings. In support of the rejection of independent claims 1, 9 and 16, the Office Action characterized the elements 2 and 3 shown in FIGS. 2 and 3 of Berrang as two modules each having a housing encapsulated by an overmold.⁵ However, Berrang's disclosure clearly and repeatedly describes its device as having a single housing ("the housing") comprising two sections.⁶ At no time does Berrang teach or even suggest that its device includes at least two interconnected modules that each comprise a respective housing to house the respective module in addition to an overmold that at least partially encapsulates the housings, as recited by Applicant's independent claims 1 and 16 or an overmold comprising a first material configured to hold at least part of a housing of one of a plurality of modules and second material, as recited by Applicant's independent claim 9.

As taught by column 11, lines 60-63 of Berrang's disclosure, medical grade epoxy (or any biocompatible polymer) 28 is used to coat and encapsulate the internal components (mounted on the ceramic substrates 24 and 25) of elements 2 and 3. Berrang clearly teaches that the outside edges of the ceramic substrates 24 and 25, or the areas over the snap domes 20 and 23 are not coated by the epoxy.⁷ Thus, the epoxy surfaces are not housings for elements 2 and 3, as the Office Action suggests because the epoxy surfaces in no way house elements 2 and 3 as required by a housing, and as explicitly stated in Applicant's independent claims. Applicant has amended the independent claims to clarify that each of the modules comprises a housing to house the

⁴ *Id.* at page 4, item 11 (emphasis added).

⁵ *Id.* at page 3, item 6.

⁶ Berrang at col. 3, l. 25 to col. 4, l. 4 and col. 9, ll. 51-62.

⁷ *Id.*

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respective module, rather than merely being a component of the module. In contrast, the epoxy surfaces in Berrang are merely components of housing sections 2 and 3.

The Office Action found that column 12, lines 8-25 of Berrang teaches that an overmold encapsulates each of the " housings " of elements 2 and 3. Applicant respectfully disagrees, and submits that the Office Action has misinterpreted the scope and content of Berrang. At column 12, lines 8-25, Berrang teaches that the epoxy surfaces 28 and 31 are covered with a gold layer, which is designed to bond directly to the outside edge of the ceramic substrates 24 and 25, thus creating a sealed, hermetic covering over the components mounted onto each of the ceramic substrates 24 and 25. FIG. 2 illustrates a gold foil 27 surrounding the entire Berrang device. This layer of gold is not an overmold, as suggested by the Office Action. Instead, the gold layer forms a single housing for elements 2 and 3, and elements 2 and 3 are two sections within the single hermetic housing.⁸

As previously discussed, the elements 2 and 3 do not have separate housings. The elements 2 and 3 of Berrang share a housing (i.e., the gold layer), and in no way have respective housings, as required by Applicant's independent claims. Nothing in Berrang teaches or suggests that elements 2 and 3 are enclosed in a housing other than the gold layer so as to be considered modules each comprising a respective one of at least two housings to house the respective modules. Furthermore, because the gold layer is the common hermetic housing for elements 2 and 3, which the Office Action characterized as "modules," the gold layer cannot be an overmold that at least partially encapsulates each of the housings of the at least two interconnected modules, as required by claims 1 and 16.

In an alternative interpretation, the Office Action characterized electronics 21 and battery 18 of Berrang as two modules, each with a respective housing at least partially encapsulated by an overmold.⁹ The Office Action further stated that electronics 21 are housed by support disc 33 and the epoxy and gold act as the overmold.¹⁰ However, Berrang's disclosure does not disclose or suggest that support disc 33 provides a housing that houses electronics 21. Again, Applicant's independent claims 1, 9, and 16 require at least two interconnected modules that each comprise a

⁸ See *id.* at col. 9, ll. 58-62 and col. 3, ll. 32-35.

⁹ Office Action dated 8/3/07 at page 3, item 6.

¹⁰ *Id.*

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respective housing to house the respective module. Berrang does not disclose that the electronics 21 are mounted to support disc 33 or that support disc 33 houses the electronics 21.

The Office Action found that because the disc 33 "is a protective element that contains or defines the negative space in which the electronics module resides, it is a housing."¹¹ Applicant respectfully disagrees with the Office Action's analysis of Berrang. Berrang does not disclose that the disc 33 defines a negative space in which the electronics 21 reside. Rather, as shown in FIG. 2 of Berrang, the disc 33 and electronics 21 are merely within the same housing section 3. Nothing in Berrang even suggests that the disc 33 plays any role in defining a space for the electronics 21.

Berrang describes piezoceramic actuators 19 and 22 that are each preferably mounted to a flexible support disc 32 and 33, respectively.¹² Snap domes 20 and 23 may be pushed to cause piezoceramic actuators 19 and 22 on flexible support discs 32 and 33 to slightly bend thereby creating a voltage pulse sufficient to activate the electronics.¹³ Support disc 33 does not house electronics 21 and, rather, provides a mounting surface for piezoceramics actuator 22. Further, as illustrated in FIG. 2, support disc 33 is located proximate to one edge of electronics 21 but not the other surfaces of electronics 21. Support disc 33 does not in any way house electronics 21. For at least these reasons, Berrang fails to disclose or suggest at least two housings, and, accordingly, fails to disclose or suggest the requirements of independent claims 1, 9, and 16.

Berrang also fails to disclose or suggest the elements of Applicant's dependent claims. For example, with respect to Applicant's claims 6 and 7, Berrang does not disclose or suggest a lead connection module does not include a mechanical lead securing mechanism that is configured to secure the external lead that is separate from the lead connection module, much less a tool-less mechanical lead securing mechanism. The Office Action reasoned that because the lead is integral to the device in Berrang, the lead connection module necessarily includes a mechanical lead securing mechanism. However, claim 1 as amended, from which claims 6 and 7 depend, specifically recite an external lead that is separable from the lead connection module. Accordingly, an integral lead and lead connection module, as disclosed by Berrang, cannot include a mechanical lead securing mechanism that is configured to secure a separate external

¹¹ *Id.* at page 7, item 21.

¹² Berrang at col. 12, ll. 32-35.

¹³ *Id.* at col. 12, ll. 35-42.

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lead. As established above, Berrang does not contemplate a lead connection module configured to accept separate cables 7 and 8.

Berrang fails to disclose or suggest each and every limitation set forth in independent claims 1, 9, and 16. Claims 2-8, 10-15, and 17-20 depend from one of independent claims 1, 9 or 16. For at least these reasons, the Office Action has failed to establish a prima facie case of non-patentability of Applicant's claims 1-20 under 35 U.S.C. §§ 102(e) or 103(a). Withdrawal of the rejection of claims 1-20 is respectfully requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Office Action's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

By:

October 2, 2007
SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Jessica H. Kwak
Name: Jessica H. Kwak
Reg. No.: 58,975